

REMARKS

This paper is being submitted in response to an Office Action dated December 20, 2007. Claims 8, 15 and 19–20 are currently pending, with claims 1–7, 9–14, 16–18 and 21 cancelled without prejudice. Claim 22 was previously cancelled without prejudice. Claim 8 is amended to clarify the scope of the claim. Support for the amendment is found throughout the specification, and particularly at page 4, lines 2–5 and page 5, lines 16–19 of the present application. No new matter is introduced by this amendment.

For the reasons given below, Applicants submit that the amended claims are in condition for allowance and notification to that effect is earnestly solicited.

Claim Rejections – 35 U.S.C. § 103(a)

1. The Examiner rejected claims 1–7 and 22 under 35 U.S.C. § 103(a) as obvious over Schumacher et al., WO 99/01450. Applicants note that claims 1–7 and 22 are cancelled, and therefore, the rejection is moot. Withdrawal is respectfully requested.

2. The Examiner rejected claims 1–21 under 35 U.S.C. § 103(a) as obvious over Schumacher et al. in view of Villani et al., WO 85/03707. As an initial matter, Applicants note that claims 1–7, 9–14, 16–18 and 21 are cancelled. With respect to the remaining claims, Applicants respectfully traverse the rejection.

To make a *prima facie* case of obviousness, the teachings of the prior art should have suggested the claimed subject matter to the person of ordinary skill in the art, and all the claim elements must be taught or suggested in the references cited by the Examiner. *In re Kotzab*, 217 F.3d 1365, 1370 (Fed. Cir. 2000). As articulated by the Supreme Court in a recent case, a combination is obvious if it is no more than the predictable use of known elements according to their established functions; and there was a reason to combine the known elements. *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. ___ (2007). To make a *prima facie* case of obviousness, “it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed.” *Id.* The initial burden to make a *prima facie* case of obviousness is on the Examiner. *In re Bell*, 991 F.2d 781, 783 (Fed. Cir. 1993). Applicants submit that the Examiner does not make a *prima facie* case of obviousness, because all the

elements of the present claims are not taught or suggested by the combination of references cited in the Office Action.

Independent claim 8, as amended, recites a process for the preparation of substantially pure desloratidine having a purity greater than 99.9%. The process comprises acidic hydrolysis of loratidine using methane sulfonic acid, pH adjustment of the hydrolyzed mixture to a pH of about 3 to about 5, treatment of the pH-adjusted mixture with an adsorbent, followed by further adjustment of pH to greater than about 9, and isolation of the product by recrystallization from a solvent system of alcohol and hydrocarbon. Applicants submit that the references cited by the Examiner, taken alone or in combination, do not teach or suggest all the elements of independent claim 8.

The Schumacher reference discloses a process for making a crystalline polymorph of desloratidine. The process involves alkaline hydrolysis of loratidine with KOH in a solvent mixture of methylated spirits followed by distilling, cooling and dissolving the mixture in methylisobutyl ketone to recrystallize the product. The Villani reference discloses a process for making desloratidine involving refluxing loratidine with NaOH in ethanol. The mixture is then distilled and acidified with glacial acetic acid, and the formed acid salt is then extracted using an organic solvent. The acid salt is then converted to desloratidine base using potassium carbonate, followed by recrystallization of desloratidine from hexane.

Applicants submit that neither the Schumacher reference nor the Villani reference, taken alone or in combination, teaches a process for making substantially pure desloratidine having a purity greater than 99.9%, as recited in claim 8. Applicants further submit that the process recited in claim 8 produces desloratidine that does not show a peak for a specific impurity in HPLC. However, as shown in the comparative examples, the desloratidine made according to the methods in the Schumacher and Villani references shows this impurity peak in HPLC (*see* page 11, line 26 to page 12, line 2 of the present application). Thus, the present claims are directed to a process that surprisingly and unexpectedly produces desloratidine in a substantially pure form, and without the impurities inherent in desloratidine made by the methods described in the cited references. Therefore, the process of claim 8 is not *prima facie* obvious.

Claims 15, 19 and 20 depend from claim 8 and incorporate all the limitations of that claim. As claim 8 is not *prima facie* obvious, the dependent claims are also not *prima facie* obvious. Withdrawal of the rejection is respectfully requested.

SUMMARY

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Please charge any additional fees or credit any overpayment to Merchant & Gould P.C.,
Deposit Account No. 13-2725.

Respectfully submitted,

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